

### **III. REMARKS/ARGUMENTS**

#### **A. Status of Claims**

Claims 38, and 47-53 are currently pending. Claims 1-37 and 39-46 have been cancelled without prejudice. Support for the amendments to claim 38 can be found throughout the application as originally filed, specifically at page 6, line 30. Support for new claims 51 and 52 can be found throughout the application as originally filed, specifically at page 18, lines 14-30. Support for new claim 53 can be found in the claims as originally filed. It is respectfully submitted that no new matter has been added by virtue of this amendment.

#### **B. Rejection under 35 U.S.C. 103 (a) over Baker et al., Swingle et al. and/or Rabasseda**

In the Office Action, the Examiner rejected claims 38-39, 46-48 and 50 under 35 U.S.C. 103 (a) over US 4,569,937 (hereinafter "Baker et al."), Swingle et al. Drugs Exptl. Clin, Res. Vol. X (8-9) (1984) (hereinafter "Swingle et al.") and/or Rabasseda, Drugs of Today Vol. 32, No. 5 (1996) pages 365-384 (hereinafter "Rabasseda"). The Examiner stated that "one of ordinary skill in the art would have been motivated to substitute Nimesulide (a NSAID) for ibuprofen (a different NSAID) in the Baker reference compositions in light of the Swingle et al., and/or Rabasseda reference teachings that Nimesulide is more efficacious, and safer with less side effects (e.g. as compared to other non-selective COX-2 inhibitor NSAID's i.e. ibuprofen)."

This rejection is traversed. Applicants respectfully submit that one skilled in the art would not be motivated to substitute the ibuprofen of the formulations of Baker et al. with Nimesulide in view of Swingle et al. and/or Rabasseda. In the April 18, 2005 response, Applicants requested that the Examiner cite the passages in the Baker reference which discuss a broad use of NSAIDs. In response, the Examiner referred to the "Background of the Invention" at columns 1-2 of Baker et al. and relied upon *In re Lemelson*, 397 F.2d 1006, 1009, 158 U.S.P.Q. 275, 277 (CCPA 1968), to support his reliance upon the Background of the Baker reference by stating that "[t]he use of patents as references is not limited to what the patentees

describe as their own inventions or to the problems of which they are concerned. They are part of the literature of the art, relevant for all they contain."

In response, Applicants respectfully submit that it is improper for the Examiner to rely solely on the Background of the Invention of Baker et al. and ignore the further teaching of this reference. The Examiner is reminded that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Accordingly, it is Applicants' position that when evaluated as a whole, the Baker reference teaches that ibuprofen provides a synergistic effect in combination with narcotic analgesics and therefore leads away from substituting the ibuprofen with nimesulide as suggested by the Examiner.

In the Advisory Action, the Examiner appeared to view the Background of the Baker reference as less preferred embodiments and stated that "the selection of a different NSAID may lead to a less than synergistic pain relief (e.g. additive) and as much may be 'less preferred'". However, Applicants submit even if the description in the Background of the Baker reference was considered to describe "less preferred embodiments", Applicants respectfully submit that the Background in combination with the secondary references do not teach or suggest the presently claimed invention.

In view of the above arguments, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Baker et al., Swingle et al. and/or Rabasseda be removed.

**C. Rejection under 35 U.S.C. 103 (a) over Baker et al., Swingle et al. and/or Rabasseda in view of Oshlack et al. (US 5,472,712) or Oshlack et al. (US 6,294,195)**

In the Office Action, the Examiner further rejected claim 49 under U.S.C. 103 (a) over Baker et al., Swingle et al. and/or Rabasseda in view of US 5,472,712 (Oshlack et al.) and US 6,294,195 (Oshlack et al.) The Examiner stated that "it would have been obvious to one of

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ordinary skill in the art . . . to utilize sustained release carriers for oxycodone including the beads/layers as taught by the Oshlack and Oshlack et al. patents for use in the Baker compositions ...".

This rejection is respectfully traversed. It is respectfully submitted that the Oshlack references do not cure the deficiencies of the Baker reference in view of the Swingle et al. and/or Rabasseda references as set forth above.

In view of the above arguments, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Baker et al., Swingle et al., Rabasseda, Oshlack et al. and Oshlack et al. be removed.

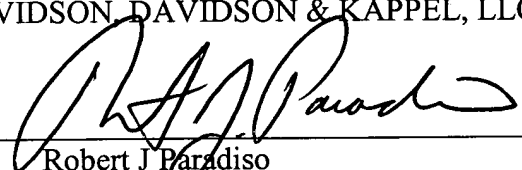
#### IV. CONCLUSION

In view of the foregoing, it is believed that the application is now in condition for allowance, and applicants respectfully request such action.

The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Respectfully submitted,  
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By: \_\_\_\_\_

  
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